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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,619	08/15/2001	Crystal M. Cunanan	ECV-5628	1609

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EXAMINER
WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
1648	6

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/930,619	CUNANAN ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) *26,27 and 29-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's election with traverse of Group I in Paper No. 5 (claims 1-20, 23-25 and 28) is acknowledged. The traversal is on the ground(s) that the search for Group I and Group II would not pose a serious burden to search. After reconsideration the restriction between Group I and Group II is now withdrawn. Therefore, claims 1-25 and 28 are under consideration in the instant office action.

The traversal of the restriction between group VI and VII is not found persuasive because the agents blocking the binding site are not directed to the same structure, one blocks the binding site of the infectious agent while the other blocks the infectious agent.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-25 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims refer to "removing a binding site" the metes and bounds of what is encompassed by "removing a binding site" is not clear. How much of a binding site must be removed in order to be effective? The specification does not provide for a way of determining at what point enough binding site is removed be able to "eliminate or reduce" infection. Is the binding site specific for the particular agent? Will removal of one

binding site be effective for all infectious agents? What is the binding site for the prion agent? Clarification of the term is required.

Claims 1-25 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to a method "of eliminating or reducing the infection in a biological material", yet do not set out sequential method steps needed to achieve the method. There is an absence or lack of clarity as to the critical method steps and resolution steps or endpoints which reads back on the preamble of the claimed method. Clarification of the method is required.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-15, 19, 21, 23, 25 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (U.S. Pat. No. 6,008,292).

The instant invention is drawn to a method of eliminating or reducing infection in a biological material by removing "binding sites" found in the biological material. The infectious agent need only be prevented or inhibited from binding. The infection contemplated (claim 2, 18, 20, 24) is a prion infection wherein the infectious agent is a prion protein. Any method that removes protein or cellular debris from a biological material would fall within the scope of the claim, by removing the undefined binding sites. The method utilizes a surfactant or denaturation agent or both, the surfactant is Tween 80 and the denaturation agent is an alcohol such as ethanol or isopropanol (claims 5-10, 17, 28). By removing the "binding site" unwanted proteins are prevented or inhibited from binding (claims 21 and 22). The method also requires treating the biological sample with a cross-linking agent, such as an aldehyde (claims 11-13). Any method that removes protein, lipids and/or cellular debris from a biological material would fall within the scope of the claims by removing binding sites. For purposes of the instant rejections the term "binding site" in interpreted to be cells and cellular debris which are comprised of phospholipid, protein and polysaccharide components.

A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process "eliminating or reducing infection in a biological sample" or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Lee et al. discloses a method of preparing collagenous biological material by treating the tissue with Denacol and 20% ethanol as well as treating tissue with a mixture of glutaraldehyde, ethanol and Tween-80 (see example 1). The tissue is then treated with polyglycidyl ether either in conjunction or following the glutaraldehyde treatment (see example 1). Ethanol and Tween agents known to be capable of solubelizing phospholipids. Glutaraldehyde is a well-known sterilization/disinfecting agent. Therefore, the instant invention is anticipated by Lee et al.

Claims 1-15, 17, 19, 21, 23, 25 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Nashef (U.S. Pat. No. 4,729,139).

The instant invention is drawn to a method of eliminating or reducing infection in a biological material by removing "binding sites" found in the biological material. See explantion above.

Nashef discloses utilizing a disinfecting solution for the processing of bioprosthetic tissue comprising formaldehyde, ethanol and tween-80 (see example 1). Ethanol and Tween agents known to becapable of solubelizing phospholipids. Formaldehyde is a well-known sterilization/ disinfecting agent. Therefore, the instant invention is anticipated by Nashef.

Claims 1-4, 18 and 20-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Abraham et al. (U.S. Pat. No. 6,599,690).

The instant invention is drawn to a method of eliminating or reducing infection in a biological material by removing "binding sites" found in the biological material. See explantion above.

Abraham et al. (U.S. Pat. No. 6,599,690) disclose a method of cleansing/treating tissue to obtain collagenous tissue and remove non-collagenous components such as cells, cellular debris, proteoglycans and glycosaminoglycans, by treatment with alkali, chelating agents and acids (see claim 1 and examples 1-9). Because cellular material and protein is removed in the processing steps disclosed by Abraham et al. infectious agents and binding site for the infectious agent are removed in the process as well. Therefore, the instant invention is anticipated by Abraham et al.

Claims 1, 3, 4, 11, 19, 23, 25 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Girardot et al. (U.S. Pat. No. 6,521,179).

The instant invention is drawn to a method of eliminating or reducing infection in a biological material by removing "binding sites" found in the biological material. See explanation above.

Girardot et al. (U.S. Pat. No. 6,521,179) disclose a method of sterilizing tissue prostheses and tissue valves. The reference provides a process of sterilization of biological tissue that has been rendered acellular either before or after cross-linking (see summary of invention). Pericardial tissue is sterilized using 25 mM EDC, 10 mM Hepes, 0.85% NaCl, 20% isopropyl alcohol, EDC is a water soluble coupling agent. The reference teaches the method steps of treating with a cross-linking agent EDC and an alcohol at concentrations effective to kill microorganisms (see claim 1). Therefore, the instant invention is anticipated by Girardot et al.

Claims 1-4, 14-16, 18-25 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated by Mirsch et al. (U.S. Pat. No. 6,121,041).

The instant invention is drawn to a method of eliminating or reducing infection in a biological material by removing "binding sites" found in the biological material. See explantion above.

Mirsch et al. disclose a method of decellularizing tissue using microorganism while leaving the matrix intact, the microorganism are subsequently inactivated (see claims 1 and 7). Subsequent processing can be used to remove the microorganism (see column 9, line 10-24). Because the art disclosed the decellularizing of the bioprosthetic tissue, the "binding sites" found in the cellular material are removed. Therefore, the instant inventions is anticipated by Mirsch et al.

Claims 1-4, 14, 15, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Vyavahare et al. (Circulation, 1997).

The instant invention is drawn to a method of eliminating or reducing infection in a biological material by removing "binding sites" found in the biological material. See explanation above.

Vyavahare et al. disclose the removal of phospholipid from a glutaraldehyde fixed bioprosthetic tissue using an ethanol wash (see table 1). Therefore, the instant invention is anticipated by Vyavahare et al.

Claims 1-15, 17-25 and 28 are rejected under 35 U.S.C. 102(a) or (e) as being anticipated Cunanan et al. (U.S. Pat. No. 6,214,054) as evidenced by Vyavahare et al. (Circulation, 1997).

The instant invention is drawn to a method of eliminating or reducing infection in a biological material by removing "binding sites" found in the biological material. See explanation above.

Cunanan et al. disclose a method of preparing bioprosthetic tissue (see claims) using a combination formaldehyde, ethanol and Tween (see claim 16) for the processing of the tissue. Vyavahare et al. provides evidence that ethanol treatment is effective at removing phospholipids from tissue (see table 1). Therefore, the instant invention is anticipated by Cunanan et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1:321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15, 17-25 and 28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,214,054 in view of Vyavahare et al. (Circulation, 1997). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method disclosed in U.S. Patent No. 6,214,054 will result in the removal of phospholipid form the fixed bioprosthetic

tissue, as evidenced by Vyavahare et al. where phospholipid removal was achieved with ethanol treatment of glutaraldehyde fixed bioprosthetic tissue (Vyavahare et al., Circulation, Table 1).

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

ULRIKE WINKLER, PHD.
PATENT EXAMINER 8/11/03